

Message

From: Orme-Zavaleta, Jennifer [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C5A111DC377411595E5B24B5D96146B-ORME-ZAVALITA, JENNIFER]
Sent: 7/13/2018 4:47:21 PM
To: Blackburn, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a080eb90549a453aaa6a357f5257c0b7-Blackburn, Elizabeth]
Subject: RE: would you mind

Thanks!

Jennifer Orme-Zavaleta, PhD
Principal Deputy Assistant Administrator for Science
Office of Research and Development
US Environmental Protection Agency

Cel
DC
RT

Personal Matters / Ex. 6

From: Blackburn, Elizabeth
Sent: Friday, July 13, 2018 12:36 PM
To: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
Subject: RE: would you mind

Deliberative Process / Ex. 5

Daily News

EPA Stalls Formaldehyde Study, Despite Congress' Direction, Agency Pledge

July 02, 2018

EPA's reluctance to advance its latest draft assessment of the human health risks of formaldehyde, allegedly because political appointees have blocked its release, appears to be at odds with Congress' direction in the agency's 2017 budget for officials to send the study to peer review and the agency's subsequent commitment to do so by Sept. 30, 2018.

It may also be at odds with the agency's Scientific Integrity Policy, which seeks to protect agency science from political interference and generally bars personnel, including political appointees, from delaying release of scientific documents.

"We continue to discuss this assessment with our Agency program partners and have no further updates to provide at this time," an EPA spokeswoman said.

EPA's Integrated Risk Information System (IRIS) program has been working for years to complete its assessment of formaldehyde's risks, a document that is expected to renew a long-running and controversial debate on whether the substance poses not just nasal cancer risks but also more worrisome leukemia risks.

Once completed, the assessment will likely drive stricter regulatory requirements, including in air toxics rules for the wood products sector, which is pending, and for natural gas turbines.

An early draft that EPA released in the Obama administration identified possible leukemia risks, a finding that industry groups have strongly criticized, citing studies showing no biological mechanism by which formaldehyde could cause leukemia.

The early draft was also strongly criticized by a National Academy of Sciences (NAS) panel, which faulted IRIS' methodology in crafting its draft and warned of a pattern of problems in how such assessments are developed in the IRIS program, that have forced the program into years of reforms amid continuing criticisms from industry and GOP critics.

The latest draft IRIS assessment, seven years in the making, has yet to be released for public comment or peer review by the NAS -- despite signs from agency officials that it was expected to be released soon.

This prompted questions about its status from three Democratic senators last month, who alleged that political appointees were delaying release of the draft which shows that the substance causes leukemia and other types of cancer.

In a [May 17 letter](#) to Administrator Scott Pruitt, Sens. Tom Carper (DE), Ed Markey (MA) and Sheldon Whitehouse (RI) said they believe officials are delaying the latest draft because it found the substance to be "carcinogenic, presenting evidence for nasopharyngeal cancer and leukemia, among other risks to human health."

They said they have learned that the latest draft IRIS assessment of formaldehyde was completed "during the fall of 2017," but that the agency has yet to proceed through the regular intra-agency review process normally undertaken before a document is released for inter-agency review, public comment, and peer review.

The senators charge that "EPA by now should have published the assessment for public comment," but that it has not because "multiple political appointees within EPA have expressed reluctance to move the assessment through the agency review process, have repeatedly set up briefings on the assessment only to later cancel them, and/or have insisted that IRIS first set up briefings for industry stakeholders before completing agency review."

The senators named Pruitt's chief of staff, Ryan Jackson, air office chief Bill Wehrum and toxics office appointee Nancy Beck as among those delaying the formaldehyde assessment's public release.

The senators asked a series of questions and sought a response from EPA by June 6. It is not clear whether the agency has responded.

New NAS Contract

The agency's failure to release the draft document comes despite a formal commitment to Congress that it will release the draft in fiscal year 2018, which ends Sept. 30.

In a [report to Congress](#) on IRIS last January, which provides details on the formaldehyde assessment, the agency noted that in the Consolidated Appropriations Act of 2017's accompanying explanatory language, "Congress requested actions related to . . . [peer] review for the draft IRIS assessment of formaldehyde," among other things.

EPA explains in the report that it has already "contracted the NAS to conduct the peer review of the revised draft IRIS assessment of formaldehyde. The draft report will go through the formal review process which will involve public comment before delivery to the NAS for peer review."

The agency said IRIS "plans to deliver an External Review Draft of its Formaldehyde Assessment for public comment and peer review in FY 2018."

The reported delay of the draft assessment also appears to violate EPA's Scientific Integrity Policy, [published in 2012](#) to protect agency science from political interference. The policy, still located on EPA's website, states that "[t]o support a culture of scientific integrity within the Agency, this policy . . . Prohibits all EPA employees, including scientists, managers, and other Agency leadership, from suppressing, altering, or otherwise impeding the timely release of scientific findings or conclusions."

Tina Bahadori, the new chief of the center overseeing IRIS, told EPA's Science Advisory Board (SAB) at its last meeting June 1 that the program has learned from its experience with the formaldehyde assessment.

"Really, formaldehyde was where we learned this lesson," Bahadori said. "Had we thought about this approach, that really we do not need to reinvent everything in the IRIS program. That we could have, when you see the recommendations from [NAS], built that assessment, rather than build it from scratch like we did, take a good part of seven or eight years, and re-start the controversies around that assessment, had we worked from settled science and just worked on developing our systematic review approaches we wouldn't be in the quagmire that we are today around formaldehyde."

Bahadori added that starting the formaldehyde assessment over from the beginning, "what it did was it lost the confidence people had in our ability to produce the assessment in a timely way. We got caught up in our own controversy. We learned from that and we are working to not make that same mistake."

Report To Congress

EPA in its report to Congress says that the IRIS program has implemented NAS' reform recommendations, both generally and specific to the formaldehyde assessment.

In particular, the report points to IRIS' efforts to adopt systematic review, an approach to searching and analyzing research intended to be more rigorous and transparent in hazard identification. EPA notes this recommendation was included in both NAS' critical 2011 formaldehyde assessment report, as well as a 2014 followup report on the overall IRIS program, which was generally supportive of EPA's efforts to address NAS' recommendations for IRIS.

EPA last publicly addressed the formaldehyde assessment four years ago, when the IRIS program [hosted a workshop](#) intended to help address the thorny scientific issues stalling the formaldehyde assessment.

Among those who attended the May 2014 meeting was Beck, who at the time represented the American Chemistry Council trade group.

According to an *Inside EPA* report from the meeting, Beck said she would "like to see an assessment completed in my lifetime" and pressed the speakers to discuss what EPA could do with the available formaldehyde data. -- *Maria Hegstad* (mhegstad@iwpnews.com)

And the one in May

Risk Policy Report - 05/22/2018

Draft EPA Study Said To Find Formaldehyde Poses Leukemia Risks

May 21, 2018

After years of additional study and scientific review, EPA has again preliminarily found that formaldehyde poses leukemia and other cancer risks, according to three Democratic senators who also say the draft finding has prompted Trump EPA appointees to block release of the assessment and they are urging Administrator Scott Pruitt to quickly release it.

Pointing to Pruitt's "back to basics" agenda for EPA, Sens. Tom Carper (DE), Ed Markey (MA) and Sheldon Whitehouse (RI) say in a May 17 letter to Pruitt that in their opinion, "assessing chemicals for their effects on human health is a basic part of EPA's mission to protect human health" and urge the administrator to "ensure there are no further efforts to delay or block the publication of this assessment that has serious implications for public health." *Relevant documents are available on InsideEPA.com. (Doc. ID: 211962)*

The senators say they have learned that the latest draft Integrated Risk Information System (IRIS) assessment of formaldehyde was completed "during the fall of 2017," but has yet to proceed through the regular intra-agency review process normally undertaken before the document is released for inter-agency review, public comment, and peer review.

They argue that "EPA by now should have published the assessment for public comment," but that it has not because "multiple political appointees within EPA have expressed reluctance to move the assessment through the agency review process, have repeatedly set up briefings on the assessment only to later cancel them, and/or have insisted that IRIS first set up briefings for industry stakeholders before completing agency review."

The senators name Pruitt's chief of staff, Ryan Jackson, air office chief Bill Wehrum and toxics office appointee Nancy Beck, as among those delaying the formaldehyde assessment's public release.

The news marks the second time in a week that the agency is facing reports that it sought to delay conservative chemical assessments. *Inside EPA* first reported May 11 that Trump administration officials' concerns are blocking release of the Agency for Toxic Substances and Disease Registry's toxicological profile of four PFAS chemicals that included risk estimates stricter than EPA's for two of the chemicals.

The senators say they believe the administration is delaying the draft formaldehyde assessment because it found the substance to be "carcinogenic, presenting evidence for nasopharyngeal cancer and leukemia, among other risks to human health."

Such a finding, while controversial, is not surprising -- EPA's last publicly available draft IRIS assessment, issued in 2010, also linked formaldehyde exposure to leukemia and nasopharyngeal risks.

But EPA never finalized the draft assessment after the National Academy of Sciences (NAS) strongly criticized its conservative risk estimates that would likely have driven a host of new regulatory requirements.

In addition, the NAS panel strongly faulted IRIS' methodology in crafting its draft assessment, warning of a pattern of problems in how the agency creates assessments for its IRIS database that have forced the program into years of reforms and continuing criticisms from industry and GOP critics.

But later NAS reports balanced the critique provided in the formaldehyde review. A 2014 NAS review concurred with the National Toxicology Program's (NTP) 2012 monograph that formaldehyde exposure could cause myeloid leukemia, while also waving aside some of industry and other critics' longtime arguments that formaldehyde exposure is unlikely to lead to systemic cancers like leukemia.

And NAS' 2014 and 2018 reviews of the IRIS program have largely praised the agency's efforts to implement the recommended reforms.

While industry officials acknowledge that formaldehyde exposure can cause nasopharyngeal risk, they say that type of cancer is much rarer and of less concern to the public than leukemia.

As a result, they have raised doubts about the agencies' conclusions and have also funded multiple studies trying to find a biological process by which formaldehyde causes leukemia.

They also sought to reanalyze a key 2010 study -- by University of California-Berkeley professor Luoping Zhang and colleagues that EPA, the National Toxicology Program and the International Agency for Research on Cancer -- have all relied upon in their conclusions that formaldehyde exposure can cause leukemia.

The Zhang study compared blood samples of Chinese workers exposed to formaldehyde with other unexposed Chinese factory workers, and concluded that chromosomal abnormalities in the exposed workers' cells were indicative of leukemia.

But last year, for example, the American Chemistry Council (ACC) touted new findings and a new award for a 2015 study it funded that re-analyzes raw data underlying the Zhang study. Authored by Ramboll Environ consultant Kenneth Mundt and colleagues, ACC's study points to flaws in the Zhang study's methods that the authors say should lead EPA and other agencies to alter their conclusions.

ACC in a press release about the studies argued that the reanalysis' findings "are important because they call into question the validity of all these recent formaldehyde assessments. The original paper failed to meet its own data quality standards and the scientific standard of reproducibility. Relying on it consequently led to unsubstantiated regulatory decisions and unwarranted outcomes."

ACC's findings also appear to have translated into industry advocacy. According to the senators' letter, ACC and Exxon Mobil "have been pressuring EPA not to release the assessment for public comment as drafted. ACC, ExxonMobil and other industry actors are said by the individuals we have communicated with to particularly object to findings related to leukemia," the senators write.

"Unfortunately, it appears that the agency may be succumbing to pressure from industry ... This is exceptionally disturbing, and lends further credence to the belief, already widely held, that EPA has been captured by industry," they say.

Such advocacy is likely responsible for delaying an assessment that was completed last fall. For example, Tina Bahadori, director of EPA's National Center for Environmental Assessment, told the agency's Science Advisory Board at its last meeting, in August 2017, that the IRIS program is working to soon release a new draft assessment of formaldehyde.

And last February, agency research officials sought to include formaldehyde as a topic of discussion at the next chartered SAB meeting, now scheduled for May 31 in Washington, D.C. Internal emails released to the Union of Concerned Scientists in response to a Freedom of Information Act request indicate that the acting head of SAB's staff office, Tom Brennan, sought to schedule a meeting with Beck, Brittany Bolen, the acting policy office associate administrator, and Richard Yamada, the deputy research office chief, to discuss the agenda for the next meeting of the chartered SAB.

In a Feb. 13 email, Brennan tells Beck, Bolen and Yamada that Jackson asked them to meet to discuss "potential topics" for the upcoming Spring SAB meeting. "We have a couple of potential items we can discuss including the war on lead, PFAS, crossagency activities and formaldehyde."

But the agenda for the SAB's May meeting -- the first since Pruitt took the helm at EPA -- includes the federal lead strategy and "EPA approaches on perfluoroalkyl substances."

Formaldehyde is not mentioned, though Bahadori and IRIS chief Kris Thayer are slated to present an IRIS "update." EPA has already contracted with NAS to review the next draft formaldehyde assessment, the senators' letter notes, but it cannot do so until the assessment completes a series of internal, inter-agency and public reviews.

But one environmentalist says it is clear that the draft assessment is being held back at EPA. It "has been stuck in [EPA] for so long it will take laxatives to get it out," says a source with the Natural Resources Defense Council. -- *Maria Hegstad*

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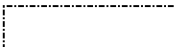

Liz Blackburn
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Mobile: Personal Matters / Ex. 6

From: Orme-Zavaleta, Jennifer
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To: Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>
Subject: would you mind

Deliberative Process / Ex. 5

tnx

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